



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,433	11/21/2005	Sang-Kyu Lee	NAMNP0103US	5833

7590 01/03/2011  
Neil A DuChes  
Renner Otton Boisselle & Sklar  
1621 Euclid Avenue  
19th Floor  
Cleveland, OH 44115

EXAMINER
----------

JOIKE, MICHELE K

ART UNIT	PAPER NUMBER
----------	--------------

1636

MAIL DATE	DELIVERY MODE
-----------	---------------

01/03/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/534,433	<b>Applicant(s)</b> LEE ET AL.	
	<b>Examiner</b> Michele K. Joiike	<b>Art Unit</b> 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 October 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8,14,16 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8,14,16 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/24/10</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt is acknowledged of a reply to the previous Office Action, filed October 18, 2010. Claims 8, 14, 16 and 18 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed July 23, 2010 that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

### ***Claim Objections***

Claim 16 stands objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

### ***Response to Arguments Concerning Claim Rejections – Claim Objection***

Applicant's arguments filed October 18, 2010 have been fully considered but they are not persuasive.

The following grounds of traversal are presented:

Applicants argue that claim 8 is directed to from whence the binding complex comes, while claim 16 recites that the cells can be cultured in vitro or in vivo.

Art Unit: 1636

Applicant's arguments have not been found persuasive for the following reasons.

There is no language in claim 16 that indicates the cell is being cultured.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 14, 16 and 18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ye et al and in view of US 2008/0097081.

***Response to Arguments Concerning Claim Rejections – 35 USC § 103 (a)***

Applicant's arguments filed October 18, 2010 have been fully considered but they are not persuasive.

The following grounds of traversal are presented:

The claimed invention includes a step of obtaining a binding complex outside the cell, and then delivering the complex into the cell. The references fail to disclose this step, as well as a DBD or DBS. Furthermore, Ye et al and US 2008/0097081 have wholly different goals. Ye et al teaches nothing more than delivery of exogenous proteins into cells, and does not teach the possibility that an extracellularly obtained binding complex might be introduced into the eukaryotic cell. US 2008/0097081 relates to using polypeptides to treat apoptosis, and while teaches formation of a fusion

Art Unit: 1636

protein, does not teach that the fusion protein could be used in the steps outlined in claim 8.

Applicant's arguments have not been found persuasive for the following reasons.

As noted by Applicant Ye et al teach a binding complex comprising a chimeric protein (protein fusion) comprising an HA epitope, a Gal4(DBD)-VP16 and a His tag. However, while they teach extracellular delivery of the fusion protein, they do not teach extracellular delivery of the whole binding complex. US 2008/0097801 remedies this deficiency by teaching a fusion protein with a PTD bound to nucleic acid molecules that are delivered from an extracellular environment into a cell. Therefore, they're teaching a complex comprised of both proteins and nucleic acids to be delivered into the cell, which is what the binding complex of claim 8 comprises. US 2008/0097801 teaches that "[s]everal examples of biologically active fusion proteins, comprising transduction domains, for direct delivery of proteins into human patients in the context of protein therapy are known in the art, including, but not limited to, the human immunodeficiency virus type 1 (HIV-1) TAT protein. These transducing proteins have been shown to be able to carry large biomolecules from the extracellular environment directly into the cytoplasm and nucleus of cells, both in vivo and in vitro. These cells can be mammalian cells (i.e. human cells). These fusion proteins have the ability to increase the delivery of plasmid DNA to the nuclei of cells in vivo and thereby increase gene expression and have been used to address a number of biological questions related to cell cycle progression and apoptosis." (paragraph 82). In other words, one would be motivated to

Art Unit: 1636

combine the references, because US 2008/0097801 teaches that fusion proteins with PTDs can be used to deliver nucleic acids (and proteins) into a cell for therapeutical purposes. Therefore, one would be motivated to modify Ye et al to deliver the entire binding complex into the cell together, instead of delivering part of the complex, one at a time. Since US 2008/0097081 also teaches that fusion proteins with PTDs are able to carry large biomolecules from an extracellular environment, and a plasmid is a large biomolecule, a fusion protein with a PTD transporting a plasmid from an extracellular environment into the cytoplasm or nucleus would yield a predictable result.

***Allowable Subject Matter***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1636

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joanne Hama can be reached on (571)272-2911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele K. Joike/  
Primary Examiner, Art Unit 1636

Michele K. Joike  
Primary Examiner  
Art Unit 1636